

Application No. 10/583,731
Amendment dated September 25, 2008
Reply to Office Action of June 25, 2008

Docket No.: 21059/0206949-US0

AMENDMENTS TO THE DRAWINGS

Amendments to the drawings not being necessary, no drawing sheets have been submitted.

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. With this amendment, claims 1, 2-18, 22-26, and 29 have been amended, no claims have been cancelled, and no claims have been added. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Thus, claims 1-26, and 29 remain pending in the application.

Support for the amendments to claims 1, 16, and 17 can be found in at least original claims 1, 16, and 17. Support for the amendment to claim 14 can be found in at least p.7, ¶3. Support for the amendments to claim 15 can be found on p.14 and the attached Wikipedia definition of Tween 80. Support for the amendment to claim 17 can found in at least p.3, l.22-25. Support for claims 22-26 can be found in at least at least Examples 1-5, p.16-24. No new matter has been added.

Objections to the Specification

The specification was objected to for numerous minor informalities. Attached herewith is a substitute specification correcting the minor informalities. Applicant respectfully requests withdrawal of the objection.

Objections to the Drawings

Figures 1-12 were objected to for using British English spellings and for not italicizing “Mw.” Applicant respectfully traverses these objections.

Regarding the use of British spelling, the MPEP explicitly instructs Examiner *not* to object to its use:

Examiners should not object to the specification and/or claims in patent applications merely because applicants are using British English spellings (e.g., colour) rather than American English spellings. It is not necessary to replace the British English spellings with the equivalent American English spellings in the U.S. patent applications. Note that 37 CFR 1.52(b)(1)(ii) only

requires the application to be in the English language. There is no additional requirement that the English must be American English. (MPEP 608.01).

Regarding the italicization of “Mw”, rule 1.84 merely suggests that legends/titles are optional and does not impose formal requirements:

(o) *Legends*. Suitable descriptive legends *may* be used subject to approval by the Office, or may be required by the examiner where necessary for understanding of the drawing. They should contain as few words as possible. 37 C.F.R. § 1.84(o)(Emphasis added).

Simply, it is not necessary for Applicant to provide new drawings to italicize part of an optional title. Applicant, therefore respectfully requests withdrawal of the objections.

Objections to the Claims

The claims 1, 2-16, 17, 25, and 29 were objected to for minor informalities. In addition, claims 22-26 were indicated as being substantially the same. Applicant respectfully traverse these objections.

Claims 1, 2-16, 17, 25, and 29 have been amended as suggested by the Examiner to overcome the minor informalities. Additionally, claims 22-26 have been amended to more clearly recite functional characteristics rather than “intended use.” Applicant respectfully requests withdrawal of the objections.

102 Rejections

Claims 1-17,22-26 and 29 were rejected under 35 U.S.C. 102(b) as being anticipated by Khamar et al (WO 03/049667). Applicant respectfully traverses this rejection.

Khamar et al. does not anticipate claims 1-17,22-26 and 29 because Khamar does not teach all of the features of independent claim 1. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegall Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 has been amended to recite “A composition comprising (i) *Mycobacterium w* and/or constituent(s) thereof as an adjuvant, (ii) an antigen, and (iii) a

pharmaceutically acceptable carrier that causes an enhanced antigen associated immune response of the antigen.” Khamar, whose inventor is the same inventor as the applicant of the present application, does not disclose a composition as claimed in claim 1, with an antigen therein. Indeed, the Examiner has recognized that the compositions of the Khamar references do not disclose an antigen and therefore has not rejected claims 18-21 which recite a specific antigen. However, it seems that the Examiner has inadvertently rejected claims 16 and 17 as being anticipated by the Khamar references as claims 16 and 17 also specifically recite an antigen. Because, Khamar does not teach all of the features of independent claim 1, Khamar does not anticipate independent claim 1 or any of the claims that depend on claim 1.

112 Rejections:

Claim 12 was rejected as being indefinite not ending with a period. Claim 13 was rejected as being indefinite for use of the modifier "preferably." Claim 14 was rejected as being indefinite for using the term "resembling". Claim 15 was rejected as being indefinite for use of the trademark/trade name TWEEN 80. In addition, the Examiner alleges that *Mycobacterium w* does not hydrolyse TWEEN 80. Claim 17 is rejected as being indefinite for use of the phrase "an antigen encoded in nucleic acids." Claim 18 was rejected as being indefinite for use of the term "derived". Applicant respectfully traverses these rejections.

Claim 12 has been amended to end with period. Claim 13 has been amended to replace "preferably" with "substantially." Claim 14 has been amended to replace "resembling" with "substantially similar." Claim 15 has been amended by substituting the chemical formula for the trade name of TWEEN 80. Please see the attached Wikipedia entry for definition of TWEEN 80. Regarding hydrolysis, Applicants note that hydrolysis is "a chemical reaction during which one or more water molecules are split into hydrogen and hydroxide ions which may go on to participate in further reactions." See attached Wikipedia definition. As described on page 14 of the specification, *Mycobacterium w* does not hydrolyze TWEEN 80. That is, when mixed with TWEEN 80, one or more water molecules are not split into hydrogen and hydroxide ions. Should the Examiner desire more information, Applicant will submit details of the hydrolysis test referenced in 7(f)(ii) on page 14 of the specification. Claim 17 has been amended to delete the phrase "antigen

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encoded in." Claim 18 has been amended to replace the word "derived" with "isolated." Applicant respectfully requests withdrawal of the rejections.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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Attachments